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VIA ELECTRONIC FILING

The Honorable Sherry R. Fallon
The U.S. District Court for the District of Delaware
844 N. King Street
Unit 14, Room 6100
Wilmington, DE 19801-3555

PUBLIC VERSION
July 18, 2023

Re: *Bard Peripheral Vascular, Inc. v. AngioDynamics, Inc.*
C.A. No. 20-1544-CFC-SRF

LETTER TO THE HONORABLE SHERRY R. FALLON
FROM DAVID E. MOORE

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Dear Judge Fallon:

Bard's decade-long litigation campaign against Angio involves three cases and nine nearly identical patents. These patents are all directed to the same idea: identifying a so-called power-injectable port. Your Honor is already involved in one case, 1:15-cv-218-JFB-SRF (the "-218 litigation"), which asserts patents that Bard has acknowledged are materially indistinguishable to those here.[1] In that case, the Court found Bard's patents to be invalid on multiple grounds, including anticipation. Bard's admissions about its own prior-art port, the Adult Titanium Port ("ATP"), played a large part in the Court's ruling. Hoping to avoid a similar fate for these patents, Bard has done an about-face, directly contradicting these sworn admissions, including matters admitted in RFAs, undisputed facts read into the record at the -218 trial, and sworn statements from Bard's corporate witnesses. This is unacceptable and prejudicial to the extreme: Bard cannot use its strategy of filing serial litigations on the same subject matter to wipe away prior admissions it now regrets. Angio respectfully requests that the Court (1) compel Bard to supplement its responses to Angio's Interrogatory Nos. 13 and 9; and (2) deem Angio's RFA Nos. 1-8, 10, 31, 32, and 34 admitted, or, in the alternative, compel Bard to amend its RFA responses.

Bard's Deficient Interrogatory Responses

Interrogatory No. 13*:** Angio requests that Bard "[d]escribe in detail any of Bard's current or former vascular access port models that have not been marketed as being power-injectable, but that are structurally capable of withstanding the pressures and flow rates of power injection procedures." (Ex. A.) This request tracks—almost verbatim—a ***stipulated fact in the -218 litigation: "at least some of Bard's current and former vascular access port models that have not been marketed as being power injectable are structurally capable of withstanding the pressures and flow rates of power injection procedures." (Ex. F, at 1066:18-23.) Bard seeks to rewrite history, now stating that "port products not designed for power injection have not been marketed for power injection." But Interrogatory 13 does not ask Bard about "port products [] ***'designed for'*** power injection"—an unclaimed concept Bard is seeking to import through claim construction. The interrogatory instead requests information related to ports that are ***structurally capable*** of withstanding the pressures and flow rates of power injection procedures. Bard's response is thus nonresponsive and deficient for this reason alone.

Moreover, Bard is not at liberty to refute the prior stipulated fact that certain of its ports were structurally capable of power injection but not marketed as such. "Generally, a stipulation entered into prior to a trial remains binding during subsequent proceedings between the parties." *Waldorf v. Shuta*, 142 F.3d 601, 616 (3d Cir. 1998); *see United States v. Robertson*, 68 F.4th 855, 861 (4th Cir. 2023) (explaining that courts have "unanimously concluded that a district court may enforce in a later trial a stipulation entered into in an earlier trial"). Bard's response also contradicts sworn testimony that its ATP—which was not "marketed as power-injectable"—was structurally capable of withstanding the pressures and flow rates of power injection. For example, Kevin Sheetz, a Bard inventor and port engineer, testified that ATP was "for sure" power injectable and capable of withstanding high flow rates and pressures—a fact confirmed by Kelly Powers, Bard's lead inventor and star trial witness. (Ex. F, at 1405:2-4); *see C.R. Bard, Inc. v. AngioDynamics, Inc.*, 2023 WL 3750649, at *18 (D. Del. June 1, 2023) (JMOL Decision) (explaining that "Bard's own admissions, along with uncontroverted test data, identify [the ATP as] capable of withstanding power injection"). Bard's response thus contradicts a ***stipulated*** fact read into the record at trial and corroborating testimony given under oath by two Bard witnesses. That cannot be allowed to stand.

[1] A cross-use agreement exists for all discovery provided in the -218 litigation and this action.

***Interrogatory No. 9*:** Angio contends that certain evidence of the power injection capabilities of prior art ports was not provided to the USPTO during prosecution of the Asserted Patents. This interrogatory tracks this evidence, requesting the facts and circumstances related to Bard's decision[2] not to provide that evidence to the USPTO, including: 1) Herts, B.R.; O'Malley, C.M.; et. al.; Power Injection of Contrast Media Using Central Venous Catheters: Feasibility, Safety, and Efficacy, AJR 2001;176:447-453 ("Herts"); 2) the Wayne Memorial Hospital Protocol; 3) the Beggs Survey; 4) Dr. Scott Trerotola's power-injection use of the HMP Vortex; and 5) Bard's testing on ATP. (Ex. A.)

Bard's response is incomplete and deficient: it addresses only Herts, not the four other references in the interrogatory. That is reason enough to order supplementation. Moreover, the evidence shows that individuals at Bard, including Mr. Powers, were aware of these documents and information during prosecution of the Asserted Patents.[3] When confronted with these facts during the meet-and-confer process, Bard refused to supplement and suggested that Angio could read Bard's witness testimony to ascertain a response. But Angio is entitled to whatever facts Bard has in its possession, not just those that were elicited in evasive testimony. *See In re Wilmington Tr. Sec. Litig.*, 2017 WL 2457456, at *2 (D. Del. June 6, 2017) (granting defendant's motion to compel where the court found plaintiff's response to an interrogatory to be inadequate "to the extent that they rely on . . . deposition testimony").

As for Herts, Bard's own evidence shows that at least Mr. Powers and those who worked on Bard's 510(k) submissions ***were*** aware of the reference during prosecution of the Asserted Patents. (*See* Ex. F, at 605:4–606:8.) But Bard's response states that it "is not aware of any evidence that Mr. Powers or anyone with a duty of candor were aware of Herts or made a decision 'not to submit certain documents and information' to the Patent Office." Yet, as just one example, Mr. Powers testified during the 2019 trial in the -218 litigation that he personally reviewed and approved Bard's PowerPort 510(k) submission, which explicitly cites to Herts. (*See* Ex. E, at 633:20-634:20.) Bard cannot now assert that it "is not aware of ***any evidence***" when this fact exists. A fulsome response thus must address the full scope of the interrogatory—not just Herts—and disclose every fact Bard knows.

Bard's Deficient RFA Responses

"When good faith requires," a party must qualify any denial and state the part admitted, even if only part of the request it true. Fed. R. Civ. P. 36(a)(4). Rule 36 also prohibits a party from denying a request based on insufficient information without reasonably inquiring into the matter. *Id.* Yet almost all of Bard's RFA responses violate this rule. Bard either (a) blanketly denies the RFAs without any qualification, contradicting its own prior representations and admissions; (b) provides responses that do not address the actual requests; and/or (c) denies based on insufficient

[2] The term "Bard" includes Bard's employees, such as lead inventor Kelly Powers.

[3] The documents and information were either produced by Bard during the -218 litigation, or were referenced in Bard's documents, all of which pre-date the issuance of the Asserted Patents. Any contention that Bard was "unaware" of them during prosecution cannot be true. For example, (1) Bard received the Wayne Memorial Protocol in response to a 2004 Bard survey; (2) the 2005 Beggs survey was commissioned by Bard to survey the extent to which doctors were power injecting ports; (3) Bard referenced its knowledge of Dr. Scott Trerotola's power-injection testing in its Product Opportunity Appraisal, which ***Kelly Powers signed*** in 2005; and (4) Bard tested the ATP itself, described the testing in its 2006 PowerPort 510(k) submission, and proffered witness testimony about it in multiple depositions and at the -218 trial. (*See* Ex. F, at 565:15–567:24; 1405:2-4.)

information, even though Bard has such information in its possession. (*See generally* Ex. C and D.) The most egregious examples include Bard's responses to RFA Nos. 1-8, 10, 31, 32, and 34.[4] These responses should be deemed admitted or, in the alternative, Bard should be compelled to serve new responses. *See Tomaszewski v. Allstate Ins. Co.*, No. 19-CV-0080, 2021 WL 1238894, at *2–5 (E.D. Pa. Apr. 2, 2021); *Thalheim v. Eberheim*, 124 F.R.D. 34, 35, 38 (D. Conn. 1988) (granting attorneys' fees for a party's "wantonly insufficient" responses to RFAs and noting that "a reviewing court should not permit a responding party to undermine the efficacy of the rule by crediting disingenuous, hair-splitting distinctions whose unarticulated goal is unfairly to burden an opposing party").

***RFA No. 1*:** Angio requests Bard admit that the 30 'Titanium PowerPort™ Equivalent Port' samples tested in the Multiple Power Injection Testing described in Bard's PowerPort 510(k) at BARD_AD_0107792-793 were ATPs. Bard's denial here is beyond the pale: Bard's ATP was the predicate device in the PowerPort 510(k). And Kelly Powers testified during the -218 trial that these ports were indeed ATPs. (*See, e.g.*, Ex. F, at 495:10-13, 558:13-20.) Bard's Response to Angio's Interrogatory No. 3 [redacted] Bard's RFA response thus refutes reality and Bard's own admissions.

***RFA No. 2*:** Angio requests Bard admit that the Multiple Power Injection Testing referenced above demonstrated that the tested ATPs had the capability to withstand multiple power injections of contrast media after septum puncture conditioning. Bard admitted multiple times during the -218 trial that the testing submitted to the FDA for Bard's PowerPort 510(k) was conducted on ATPs. (*See* Ex. F, at 495:10-13, 558:13-20.) And Bard's 510(k) submission makes clear that the purpose of this testing was to "[d]emonstrat[e] [] the capability of the port to withstand multiple power injections of contrast media after septum puncture conditioning." (*See* Ex. G.) Again, Bard's response refutes reality and Bard's own prior admissions.

RFA Nos. 3-5*:** Angio requests Bard admit that the ATP samples tested in Bard's 510(k) submission on ***power-injectable ports are "power injectable ports." In response, Bard simply "admits" that its PowerPort 510(k) recites certain language noting that the PowerPort system sample (*i.e.*, the 30 ATPs) "met the multiple power injection test requirements." But that is not what the RFAs request. They instead ask Bard to admit that the tested samples were power injectable. While the RFA includes a term for which the parties have competing claim constructions, a reasonable response would account for either party's proposed definition. Indeed, RFAs 4 and 5 account for each party's construction of this term. Responding that the ATP samples "met the multiple power injection test requirements" set forth by the FDA is not responsive.

***RFA No. 6*:** Angio requests Bard admit that the ATP was on sale and publicly available before March 4, 2005. Bard responds that "[p]rior to March 4, 2005, Bard sold port products,

[4] Bard's objections to the definition of ATP is also inappropriate. ATP has been a primary reference for the better part of a decade—and it was used to invalidate Bard's claims in the -218 litigation. Yet, Bard now contends ATP "includ[es] multiple product lines, including plastic ports." But Bard is playing games. ATP is a Bard product. Bard's own witnesses have testified about it many times, including Mr. Powers during the -218 trial, which is explicitly referenced in Angio's Definition. As defined ATP is the same port Bard identified as the predicate device in its PowerPort 510(k). Bard has also referenced the "ATP" in its own discovery responses. (*See* Ex. H.) It is also clear the Adult ***Titanium*** Port does not include ***plastic*** ports. Bard's assertion to the contrary is not in "good faith." And to the extent Bard would admit to any RFA for an ATP encompassed by any part of Angio's Definition, Bard must say so. *See* FRCP 36(a)(4).

including both plastic and titanium port products." But this is nonresponsive to the actual RFA. Angio requested that Bard admit that the ***ATP*** was on sale and publicly available—not any "port product."

***RFA No. 7*:** Angio requests Bard admit that the same 30 ATPs referenced in the previous RFAs met the tolerance requirements that Bard deemed necessary for acceptable performance during power injection procedures. Yet Bard denies this request, contradicting Mr. Powers's -218 trial testimony where he testified that the ATPs tested for Bard's PowerPort 510(k) "met the tolerance requirements of the ultimate design" of the PowerPort. (See Ex. F, at 495:10-19; *see also id.* at 496:15-22; 565:15–567:24.)

***RFA No. 8*:** Angio requests Bard admit that at least some of Bard's ATPs "that in the natural variability of manufacturing would have been in the mix" of ports that were "publicly available" and on-sale before March 4, 2005, "met the tolerance requirements of the ultimate design" of the PowerPort, as well as "the precision requirements [Bard] had determined to be necessary" for the PowerPort to be power-injectable. Mr. Powers already conceded this point during the -218 trial, which is cited in the RFA itself. Bard is not at liberty to deny this fact here.

***RFA No. 10*:** Angio requests Bard admit that it never submitted specific documents and information to the USPTO during prosecution, reexamination, or any other proceeding before the USPTO, of any of the Asserted Patents. Bard denies this request. But Bard's response is, at minimum, contradicted by the prosecution histories of the Asserted Patents, and moreover is directly at odds with its stipulation in the -218 Litigation that the Herts reference was not provided to the USPTO during prosecution of those related patents. (Ex. F, at 1067:5-13; *see also* Ex. L.)

***RFA No. 31*:** Angio requests Bard admit it knew commercially-available ports were being used for power injection procedures before March 4, 2005. Bard claims it "lack[s] information sufficient to admit or deny this Request." That is untrue. But Bard doesn't lack sufficient information. Bard cited *Herts* to the FDA to show that its ATP was being used for power injection as early as 2001. (*See* Ex. G.) Bard's PowerPort Project Summary, signed by Powers, states that, based on "[p]ersonal communication with Dr. Scott Trerotola" on March 1, 2005, Penn Medical proved that the "HMP Vortex [prior-art port] can withstand power injection pressures, and they now use it for this purpose." (*See* Ex. I; s*ee also* Ex. F, at 579:21–581:6; *see also* Ex. J, at 216:7-20.) On top of that, Bard conducted surveys of practitioners who were performing power injection prior to March 4, 2005, and even solicited protocols from those who were. (*See* Ex. G; s*ee also* Ex. I.) Bard's response is improper.

***RFA No. 32*:** Angio requests Bard admit that, prior to the filing date of any of Asserted Patents, at least some implantable medical devices already included X-ray visible letters. Bard again claims that it "lack[s] information sufficient to admit or deny this Request." But in the -218 litigation, Bard stipulated that it was known in the medical field prior to the filing date of any of the related asserted patents that "medical devices intended to be implanted in humans could have radiographic markers...that could identify information about the device after implantation." (*See* Ex. F, at 1066:24–1067:4.) Bard has also recognized the existence of prior art that included *radiographic letters* in the -218 litigation. (See Ex. K, at ¶¶980–81). Bard cannot now deny this fact.

***RFA No. 34*:** Angio requests Bard admit that Angio began engraving the letters "CT" on its titanium SmartPort before Bard began engraving the letters "CT" on its titanium PowerPort. Bard claims that it "lack[s] information sufficient to admit or deny this Request." But this is contradicted by Bard's documents and witness testimony from the -218 litigation. (*See* Ex. F, at 601:3–602:22 (Powers admitting that Bard engraved "CT" on its titanium port after Angio).)

Respectfully,

/s/ David E. Moore

David E. Moore

DEM:nmt/10908508
Enclosures
cc: Clerk of Court (via hand delivery)
Counsel of Record (via electronic mail)